IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF TENNESSEE
NASHVILLE DIVISION

UNITED STATES OF AMERICA *ex rel.* JEFFREY H. LIEBMAN and DAVID M. STERN, M.D.,	)	Case No.: 3:17-cv-00902
Plaintiff-Relators,	)	JUDGE CAMPBELL MAGISTRATE JUDGE HOLMES
v.	)	
METHODIST LE BONHEUR HEALTHCARE and METHODIST HEALTHCARE-MEMPHIS HOSPITALS,	)	
Defendants.	)	

UNITED STATES' MEMORANDUM OF LAW IN SUPPORT OF ITS MOTION TO EXCLUDE EVIDENCE RELATING TO PATIENT CARE AND OUTCOMES

Pursuant to Rules 26 and 37 of the Federal Rules of Civil Procedure and Rules 402 and 403 of the Federal Rules of Evidence, the United States of America ("United States") submits this memorandum of law in support of its motion *in limine* to exclude Defendants Methodist Le Bonheur Healthcare and Methodist Healthcare-Memphis Hospitals ("Methodist") from presenting evidence regarding patient care, the existence or non-existence of adverse patient outcomes, any purported benefit to patients and any other evidence relating to the impact on Methodist's patients resulting from Methodist's relationship with The West Clinic, P.C. ("West"). Methodist has not disclosed evidence of patient care or patient outcomes, including any patient records, in its Initial Disclosures or in response to any discovery requests in this action. Thus, it cannot rely on patient care or outcomes to defend this case.

Further, evidence relating to patient care or patient outcomes is not relevant. The United States has not alleged that any patients were harmed because of the underlying conduct that supports its claims that Methodist violated the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b ("AKS"). Methodist admits that the United States is not required to show patient harm to establish an AKS violation. (Exhibit A.) Methodist also cannot defend its alleged unlawful conduct by claiming it intended a benefit for patients or that a lack of patient harm negates intent.

Methodist also cannot use evidence of patient outcomes to show that there was no unlawful remuneration because West performed services for Methodist. An AKS violation may be established even if services were rendered. It also fails to address the myriad allegations of remuneration unrelated to the services West performed. To the extent the argument is predicated on notions underlying amendments to an AKS safe harbor, it also fails for the reasons in the accompanying motion *in limine*. Therefore, the Court should preclude Methodist from submitting any evidence regarding patient care or outcomes and eliciting any testimony relating thereto.

BACKGROUND

A. Summary Of The United States' AKS Allegations

In this action, the United States has alleged that Methodist violated the AKS by paying unlawful remuneration to West in exchange for patient referrals. (ECF No. 235 at ¶ 353.) The payments were made through the various transaction documents entered into between Methodist and West that were in effect from January 1, 2012 through December 31, 2018, including an Asset Purchase Agreement ("APA"), a Professional Services Agreement ("PSA"), a Leased Employee and Administrative Services Agreement ("LEA") and a Management Services/Performance Improvement Agreement ("MSA"). (*Id.* at ¶¶ 3, 10.) The relationship between Methodist and West terminated on February 23, 2019. (*Id.* at ¶ 348.)

The United States does not allege that all the payments were fraudulent or that West did not perform any services or satisfy any of the obligations under the various contracts. Rather, the United States alleges that agreements with West were a vehicle to disguise the kickbacks. For example, under the APA, Methodist paid West for assets that Methodist did not acquire. Under the PSA, Methodist paid West for certain professional services performed by nurse practitioners who were leased to Methodist under the LEA. Kickbacks also came through payments to West under the MSA, even though West did not perform all the base management services required by the MSA, in all the locations. Methodist even agreed to and did increase the amount it paid to West under the MSA two years into the contractual relationship, knowing that West had not performed all the base management services under the MSA. Methodist also paid West millions of dollars under the MSA knowing that Erich Mounce, West's Chief Executive Officer who was leased full-time to Methodist under the LEA, also was the Administrator tasked with oversight for West's performance of the MSA. Further, kickbacks were paid because, under the LEA, Methodist paid the entire salary for West employees and an independent contractor who were leased full-time to Methodist and still performed work for West, including Mr. Mounce and Ronald Davis, West's Chief Financial Officer. In addition, Methodist paid kickbacks to West by allowing West to continue operating its business out of a location Methodist acquired under the APA, and then later out of a location that Methodist owned without requiring West to pay any rent. *See, e.g.*, ECF No. 296-1 at 4-9 (further detailing the alleged unlawful remuneration). The United States contends that because Methodist violated the AKS, it submitted false claims to Medicare certifying its compliance with the AKS, which constitute violations of the False Claims Act, 31 U.S.C. §§ 3729-3733 ("FCA").

B. Evidence Of Patient Care Or Outcomes Has Not Been Produced

Methodist served its Supplemental Initial Disclosures to the United States on June 24, 2022. (Exhibit B.) Methodist did not identify evidence of patient care or patient outcomes as being information that it may use to support its claims or defenses in this action. Nor has it disclosed information sufficient to confirm that there were no adverse patient outcomes with any Methodist patient over the relevant time period, without limitation to adult oncology patients or Medicare patients.

On June 28, 2022, the United States served Methodist with document requests seeking the "documents Methodist intends to rely on to defend the allegations in the Complaint in Intervention," to which Methodist responded on July 28, 2022 indicating it was not aware of any additional non-privileged documents that were responsive to the request that had not been produced. (Exhibit C at 11-12.)

Methodist admits that it did not produce any patient records. (Exhibit A.) Methodist also did not produce documents that demonstrate that there were no adverse patient outcomes for any of the thousands of patients Methodist treated during the relevant time period.

C. The Evidence Methodist Intends To Offer Relating To Patient Care And Outcomes

RFA 3 states: "Admit that You have not identified any adverse impact on Methodist's patient outcomes due to the structure of the Affiliation Agreements." (ECF No. 271-6 at 4). RFA 5 states: "Admit that You have not identified any adverse patient outcomes that resulted from the co-management of any Methodist patients' care by the West Cancer Center." (*Id.* at 4-5.) The United States refused to respond to Methodist's RFAs 3 and 5, as it sought information that is not relevant, and the United States otherwise does not have sufficient information to admit or deny the requests, which now is the subject of a pending motion. (ECF No. 301.)

Methodist has informed the Court that it intends to introduce the responses to RFAs 3 and 5 (which is seeks to be deemed admitted), as "part of its defense" to show "that, contrary to the government's allegations, the affiliation was designed to—and did—improve the overall quality, efficiency, and effectiveness of the cancer care delivered at Methodist, as was the parties' express intent in creating and co-managing the cancer center." (ECF No. 301 at 1-2.) The United States has not made any allegations about the parties' intentions to improve cancer care and more specifically that Methodist did not intend to improve cancer care.

In RFAs 7 and 8, Methodist also asked the United States to admit that it made certain statements published in connection with amendments to a safe harbor to the AKS, which reference impacts on patient care, as detailed in the United States' response to Methodist's motion to determine the sufficiency of the United States' responses to these requests. (ECF No. 303.)[1] Methodist also informed the Court that it intends to use the responses to RFAs 7 and 8 to "show that, contrary to the government's allegations, the intent of the parties' affiliation was to promote the delivery of more efficient and better coordinated care through various innovations achieved through the parties' agreements." (ECF No. 303 at 1.) Again, there are no such allegations relating to Methodist's intentions as far as patient care.

Methodist further states: "'Along with this evidence of improved care, Methodist also will show that the government has not identified any adverse impact on patient outcomes resulting either from the "structure of the Affiliation Agreements,' (RFA No. 3), or 'the co-management of any Methodist patients' care by the West Cancer Center,' (RFA No. 5)." *Id.* at 2.

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[1] The United States is filing simultaneously herewith a motion *in limine* to exclude evidence relating to safe harbors to the AKS, which it refers to and incorporates herein, as well as its responses to Methodist's motion to determine the sufficiency of RFAs 3, 5, 7 and 8.

Because Methodist seeks admissions from the United States that it intends to introduce into evidence relating to patient outcomes and patient care, the United States now files this motion *in limine*, as it also directly impacts Methodist's motions to determine the sufficiency of the United States' responses to RFAs 3, 5, 7 and 8.[2]

ARGUMENT

I. METHODIST CANNOT RELY ON EVIDENCE IT DID NOT DISCLOSE

Evidence of patient care or patient outcomes should be excluded because Methodist did not produce any evidence sufficient to determine the impact on all of Methodist's patients as a result of the transaction with West. It is axiomatic that parties may not use evidence that they did not disclose in discovery, unless the failure to disclose such evidence was substantially justified or is harmless. FED. R. CIV. P. 37 (c). There is no substantial justification for Methodist to fail to disclose evidence it intends to introduce to defend the United States' claims. Methodist seemingly knew all along that it intended to rely on evidence of patient care and patient outcomes, yet it did not produce documents underlying the defenses it intends to assert.

If Methodist claims that the presentations or marketing documents it produced as to improvements in patient care are sufficient, it is wrong. Such self-serving documents are hearsay and not probative of any issues. Methodist cannot claim that because it treated more patients, cancer care was improved. Methodist would need to show that absent the arrangement with West,

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[2] Requests for admission are not a discovery device but are used to narrow the disputed issues at trial. *Misco, Inc. v. U.S. Steel Corp.*, 784 F.2d 198, 205 (6th Cir. 1986), *Tolson v. Washburn*, Case No. 3:19-00175, 2022 WL 1479945, at *4 (M.D. Tenn. May 10, 2022) (Newbern, J.). Fact discovery has concluded. The Court has made clear that it will not move the November 2023 trial date. Not only will an evidentiary ruling on this discrete issue narrow the disputed issues for trial, it will inform the parties on matters concerning the proper subjects of expert testimony and for summary judgment, thereby reducing, if not avoiding, further motion practice before the Court.

such patients would have not received care or would have received inadequate care. Methodist also would need to produce evidence of the actual number of patients who were treated at Methodist before and during its relationship with Methodist and evidence regarding their outcomes from treatment to show that its arrangement with West improved cancer care. There is no such evidence in the case. To allow Methodist to introduce evidence that it has not produced and that the United States has not been able to explore in discovery would be prejudicial.

Thus, absent producing documents on such issues, Methodist should not be permitted to make broad assertions that there were no adverse patient outcomes to any Methodist patient, including those not seeking oncology treatment. Similarly, Methodist should not be permitted to assert generally that patient care was improved because of its relationship with West.

II. EVIDENCE OF PATIENT CARE AND OUTCOMES IS NOT RELEVANT

The Federal Rules of Evidence define "relevant evidence" as "evidence having any tendency to make the existence of any fact that is of consequence to the determination of the action more probable or less probable than it would be without the evidence." FED. R. EVID. 401. "Evidence that is not relevant is not admissible." FED. R. EVID. 402.

The United States has not made any allegations, one way or the other, concerning whether patients were harmed because of the unlawful conduct. As Methodist has acknowledged (Ex. A), patient harm is not an element of the AKS. Similarly, the lack of patient harm does not absolve a defendant from liability under the AKS. Nor is an intent to benefit patients a basis to defend a kickback violation.

To prove an AKS violation, the United States must show that Methodist paid remuneration to West with the intent to induce referrals. *See U.S. ex rel. Goodman v. Arriva Medical, LLC*, 471 F. Supp. 3d 830, 833 (M.D. Tenn. 2020) ("Some AKS violations are obvious; for example, if a

hospital CEO 'paid kickbacks to physicians who referred Medicare and Medicaid patients to' his hospital, then he probably violated the AKS."). There is no element of the AKS that requires the United States to show that patients were harmed because of the unlawful kickbacks. The United States did not make any allegations with respect to patient outcomes in the Complaint in Intervention.

Similarly, neither the absence of patient harm nor any benefit to patients can be used to show a lack of intent to violate the AKS. Even if the remuneration that Methodist paid to West had legitimate purposes (*i.e.*, to help patients by developing a comprehensive cancer center), courts have routinely found that an AKS violation can be established where "one purpose" of the remuneration was to induce referrals. *See, e.g.*, *U.S. ex rel. Lutz v. Mallory*, 988 F.3d 730, 741 (4th Cir. 2021); *U.S. v. Borrasi*, 639 F.3d 774, 782 (7th Cir. 2011); *U.S. v. McClatchey*, 217 F.3d 823, 835 (10th Cir. 2000); *U.S. v. Davis*, 132 F.3d 1092, 1094 (5th Cir. 1998); *U.S. v. Kats*, 871 F.2d 105, 108 (9th Cir. 1989); *U.S. v. Greber*, 760 F.2d 68 (3d Cir. 1985). Although the Sixth Circuit has not yet weighed in on the issue, this Court has concluded that an AKS violation can be established where only one purpose of the remuneration is to induce referrals—and not the only purpose. *See, e.g.*, *U.S. v. SouthEast Eye Specialists, PLLC ("SEES")*, 570 F. Supp. 3d 561, 579 (M.D. Tenn. 2021) (Crenshaw, C.J.) ("As previously explained, the Circuit Courts that have addressed the issue have uniformly held that if at least one purpose of the remuneration is in return for a referral, then the statute has been violated. Hence, Plaintiffs need only forward plausible allegations that *a* purpose of Defendants' scheme was to induce referrals.") (emphasis in original); *Arriva Medical, LLC*, 471 F. Supp. 3d at 833.

As this Court also has recognized, "the Anti-Kickback Statute itself provides that actual knowledge of the statute or the specific intent to violate it is not required." *SEES*, 570 F. Supp. 3d

at 581. In *SEES*, the Court stated: "SEES may be truly altruistic towards its referring optometrists, but its nobility of purpose and spirit cannot run afoul of the Anti-Kickback Statue." *Id.* at 578.

Whether Methodist intended for patients to have some benefit does not impact whether Methodist also had the requisite intent to violate the AKS. Similarly, even if there was some benefit to patients from Methodist's arrangement with West or if West actually performed services for Methodist, that does not mean there was no AKS violation. The United States only needs to show that Methodist also paid West in exchange for referrals in violation of the AKS.

To the extent Methodist intends to introduce patient outcomes to show that there was no remuneration since West purportedly provided services, it also is irrelevant. The United States' allegations of unlawful remuneration are not based solely on payments Methodist made for services West failed to perform under the MSA. Rather, the United States is claiming that there were myriad ways in which Methodist paid West remuneration through the course of the parties' relationship. For example, the United States alleges that West employees who were leased full-time to Methodist continued to do work for West, including opening new West locations, and that West operated its principal place of business out of a Methodist location without paying rent to Methodist. Patient outcomes are entirely irrelevant to Methodist allowing West to operate for free or paying the salary of West employees that continued to do work for West.

Finally, to the extent that Methodist intends to use patient outcomes to try to mount a backdoor safe harbor defense, it also is not relevant, for the reasons in the accompanying motion *in limine*.

In sum, patient care and outcomes are not relevant and are inadmissible under Rule 402.

III. EVIDENCE OF PATIENT OUTCOMES IS PREJUDICIAL AND CONFUSING

Even though Methodist should not be allowed to introduce evidence of patient outcomes that it has not disclosed and that are not relevant to establish any element of the AKS or to any defense Methodist is asserting, evidence of patient outcomes also should be excluded under Rule 403. Courts may exclude otherwise "relevant evidence if its probative value is substantially outweighed by a danger of" … "unfair prejudice, confusing the issues, [or] misleading the jury." FED. R. EVID. 403. This Court also should exclude such evidence because it would be confusing and misleading to the jury if Methodist inserted patient outcomes into this case, as well as prejudicial to the United States.

It is also prejudicial to the United States and confusing to the jury if Methodist is permitted to introduce evidence of patient outcomes to show that West performed services under the MSA. As noted above, it is not a defense for Methodist to show that West performed services or that there was some benefit from those services. Introduction of such evidence would be misleading, particularly given that the United States is not claiming that West failed to perform any services for the entire seven years or that the only remuneration paid was through the MSA.

If Methodist is allowed to tell the jury that it intended to improve cancer care, that there was some benefit to cancer patients or that there was no harm done to patients, particularly given that Methodist did not disclose patient records, it also would confuse and mislead the jury into believing that because cancer care was improved Methodist should not be liable. Such evidence also would be prejudicial to the United States.

Evidence of patient outcomes also is likely to result in a jury believing that Methodist is relying on a safe harbor it has not invoked. As Methodist has articulated, its proposed introduction of evidence as to patient outcomes is predicated, in part, on notions underlying a safe harbor to the

AKS that it is not asserting as an affirmative defense. For the same reasons in the accompany motion *in limine* relating to safe harbor evidence, Methodist also should not be allowed to introduce evidence of patient outcomes to the extent it relates to the safe harbor.

In sum, evidence of patient harm lacks any probative value. It would waste judicial time on the presentation of evidence that does not go to any issue or defense in the case, and it could confuse and mislead the jury that the United States has some burden to show patient harm or that Methodist could not be found liable in the absence thereof, and result in prejudice to the United States.

CONCLUSION

For the foregoing reasons, and those set forth in the United States' accompanying submissions, the Court should preclude the introduction of any evidence, whether in a motion for summary judgment or at trial, relating in any way to patient care or outcomes, patient harm (or the lack thereof), and any intent to improve patient care.

Dated: January 13, 2023

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CERTIFICATE OF SERVICE

I hereby certify that on January 13, 2023, a true and correct copy of the foregoing was served via email to the following:

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